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David C. Jenkins
Eckert Seamans Cherin & Mellott, LLC
600 Grant Street, 44th Floor
Pittsburgh, PA 15219

EXAMINER	
RINES, ROBERT D	
ART UNIT	**PAPER NUMBER**
3626	

DATE MAILED: 10/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/020,364	CLEMENTI, WILLIAM A.	
	Examiner	Art Unit	
	Robert D. Rines	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 May 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Notice to Applicant

[1] This communication is in response to the amendment filed 30 May 2006. Claims 1-21 are pending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

[2] Claims 11 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yarin et al. (United States Patent #6,294,999) in view of Cummings, Jr. (United States Patent #5,301,105).

[A] As per claim 11, Yarin et al., teaches a computer-readable medium structured to communicate with smart packages for medicines through an electronic medium and containing instructions for determining the compliance of a patient with a medicine regimen (Yarin et al.; col. 5, lines 34-48), by: collecting data from said smart packages (Yarin et al.; col. 7, lines 15-21); and analyzing data to determine the compliance level of the patient (Yarin et al.; col. 11, lines 10-26).

[i] The invention of Yarin et al. is primarily directed to the software and hardware components of a "smart tray" and associated mechanisms for collection of compliance data (Yarin et al.; col. 5, lines 14-20 and lines 34-47). Although it is clear that Yarin et al., intends that the invention be practiced with more than a single patient participant, Yarin et al., fails to specifically teach storing data in a database regarding a plurality of patients and a plurality of medicines. Similarly, although Yarin et al. includes consideration of data that is clearly collected from outside sources (i.e., stakeholders) such as drug side effect and contraindicated drug-drug interactions, Yarin et al., fails to expressly disclose the step of electronically collecting input data from stakeholders.

[ii] However, Cummings teaches storing said data in said database (Cummings Jr.; col. 4, lines 30-39); storing a database which includes information regarding a plurality of patients and a plurality of medicines (Cummings, Jr.; col. 4, lines 30-39, col. 5, lines 9-14, and col. 9, lines 47-52); and collecting input data from said stakeholders through said electronic communication medium (Cummings Jr.; col. 4, lines 53-62, and col. 8, lines 15-21).

[iii] It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Yarin et al., with those of Cummings. Such combination would have resulted in a system and method capable of collecting compliance data from individual patients using a medication "Smart Tray" that is capable of monitoring and reporting to third parties a patient's compliance with various treatment regimens, including medication regimens (Yarin et al.; col. 3, lines 20-25). Further, such a system would serve to

enter and store the colleted compliance data in databases (Cummings, Jr.; col. 4, lines 30-39) such that analysis of the data could serve to enhance periodic monitoring and review of a patient's adherence to health recommendations (Cummings, Jr.; col. 8, lines 22-34). The motivation to combine the teachings would have been to provide enhanced compliance data through a system that facilitates complete integration of the essential elements to provide patients with complete and comprehensive health care (Cummings, Jr.; col. 1, lines 54-60). Further motivation would have been to enhance systems for the analysis of treatment protocols and diagnostic smart systems that serve as aids in treatment planning and diagnostic test selection (Cummings, Jr.; col. 1, lines 65-68 and col. 2, lines 1-2).

[B] As per claim 14, Yarin et al., teaches: a) the step of collecting data from said smart packages is an on-going process and said analysis to determine a compliance level is repeated over time (Yarin et al.; col. 7, lines 15-21, and col. 49-57); and b) said step of analyzing data to determine the compliance level of the patient is repeated over time (Yarin et al.; col. 7, lines 15-21, and col. 49-57).

[i] Regarding claim 14, the obviousness and motivation to combine as discussed with regard to claim 11 above are applicable to claim 14 and are herein incorporated by reference.

[3] Claims 12-13, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yarin et al. and Cummings, Jr., as applied to claim 11 above, and further in view of Aten et al. (United States Patent #4,823,982).

[A] As per claim 12, Yarin et al., teaches that the data collected from said stakeholders includes data regarding the side effects of a medicine and interactions between medicines (Yarin et al.; col. 3, lines 65-67 and col. 4, lines 1-11). Yarin et al., fails to expressly teach inclusing the expected results of a medication or treatment protocol in the collected data.

[i] However, Aten et al., teaches collection of data regarding the expected results of medicines (Aten et al.; col. 15, lines 5-16).

[ii] It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Yarin et al., and Cummings, with those of Aten et al. Such combination would have resulted in a prescription/medication monitoring system that enabled the user to determine whether two or more medicaments are contraindicated (Yarin et al.; col. 4, lines 1-5). Further, such as system would include a measure of the effectiveness of the doses taken (Aten et al.; col. 15, lines 5-16). The motivation to combine the teachings would have been to use gathered patient compliance data to compare the actual dosing intervals to the prescribed dosing intervals to determine how well the actual medication levels matched the prescribed levels (Aten et al.; col. 15, lines 5-15). Further motivation would have been to provide

a thorough evaluation of patient compliance to the prescribed regimen (Aten et al.; col. 15, lines 22-25).

[B] As per claim 13, Cummings, teaches that the data collected from said stakeholders includes data regarding diagnostic medical test results, and data regarding the adherence to exercise and diet regimens by a patient (Cummings Jr.; col. 8, lines 22-34, and col. 10, lines 18-26).

[i] Regarding claim 13, the obviousness and motivation to combine as discussed with regard to claims 11 and 12 above are applicable to claim 13 and are herein incorporated by reference.

[C] As per claim 15, while Cummings teaches allowing stakeholders to access patient data through an electronic medium (Cummings, Jr.; Abstract, col. 1, lines 54-60, and col. 8, lines 15-21), Cummings fails to teach a calculated compliance value or that a calculated compliance value is among the patient data accessible by stakeholders. Although Yarin et al., teaches the further step of analyzing data to determine a compliance-behavior level of the patient (Yarin et al.; col. 5, lines 25-32), Yarin et al., does not teach quantifying a patient's compliance-behavior level as a value or further allowing stakeholders to access a quantified compliance value or rating.

[i] However, Aten et al. teaches analyzing data to determine a compliance-behavior value of the patient (Aten et al.; col. 14, lines 67-68 and col. 15, lines 1-4).

[ii] Regarding claim 15, the obviousness and motivation to combine the teachings of Yarin et al., Cummings, as discussed with regard to claim 11 above are applicable to claim 15 and are herein incorporated by reference.

[ii] Regarding the addition of the teachings of Aten et al. to claim 15, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Yarin et al. and Cummings with those of Aten et al. Such combination would have enabled the compliance level assessment of Yarin et al. (Yarin et al.; col. 5, lines 25-32) to be enhanced by calculating several compliance scores from patient data (Aten et al.; col. 14, lines 67-68). The motivation to combine the teachings would have been help patients take medications per a prescribed schedule and to evaluate the patient's actual compliance to the regimen (Aten et al.; col. 2, lines 54-65). Further motivation would have been to provide an evaluation of patient compliance to the prescribed regimen and the probable effectiveness of the drug therapy (Aten et al.; col. 15, lines 17-25).

[4] Claims 1-4, 8-10, 16-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yarin et al. in view of Cummings, Jr., and further in view of Snowden et al., (United States Patent Application Publication #2002/0026332).

[A] As per claim 1, Yarin et al., teaches a method of disseminating medical information to increase patient compliance with a medical regimen, said method comprising the steps of: providing medicine to a patient in a smart package (Yarin et al.; Abstract, and col. 3, lines 20-40); providing a device structured to allow said smart packages to interact through an electronic communication medium (Yarin et al.; col. 3, lines 42-51); collecting data from said smart packages (Yarin et al.; col. 7, lines 15-21); and analyzing data to determine the compliance level of the patient (Yarin et al.; col. 11, lines 10-26).

[i] Yarin et al., fails to expressly disclose creating a database with a plurality of medicines and a plurality of patients, a system structured to allow a plurality of stakeholders to electronically access the database and input data, storing patient compliance data in the database, creating patient reports, and making reports accessible to a patient.

[ii] However, Cummings teaches creating a database which includes information regarding a plurality of patients and a plurality of medicines (Cummings, Jr.; col. 4, lines 30-39, col. 5, lines 9-14, and col. 9, lines 47-52); providing a system structured to allow a plurality of stakeholders to access said database and input data into said database through an electronic communication

medium (Cummings, Jr.; Abstract, col. 1, lines 54-60, and col. 8, lines 15-21); collecting input data from said stakeholders in said database through an electronic communication medium (Cummings Jr.; col. 4, lines 53-62, and col. 8, lines 15-21); storing said data in said database (Cummings Jr.; col. 4, lines 30-39); and creating a patient report for each said patient having data relevant to each said patient (Cummings Jr.; col. 8, lines 15-34, col. 9, lines 39-46, and col. 12, lines 34-43). Cummings, fails to teach patient access to patient reports.

[iii] However, Snowden et al., teaches allowing each said patient to access his or her patient report through an electronic communication medium (Snowden et al.; Abstract and paragraphs [0075] [0104]).

[iv] It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Yarin et al., with those of Cummings, Jr., and further with those of Snowden et al. Such combination would have resulted in a system and method capable of collecting compliance data from individual patients using a medication "Smart Tray" that is capable of monitoring and reporting to third parties a patient's compliance with various treatment regimens, including medication regimens (Yarin et al.; col. 3, lines 20-25). Further, such a system would serve to enter and store the colleted compliance data in databases (Cummings, Jr.; col. 4, lines 30-39) such that analysis of the data could serve to enhance periodic monitoring and review of a patient's adherence to health recommendations (Cummings, Jr.; col. 8, lines 22-34). Additionally, such a system would have enabled compliance reports to be stored in a secure repository along with other personal medical records owned and

controlled by the patient such that the patient could access reports and make such reports accessible to appropriate care providers, insurers and suppliers (Snowden et al.; Abstract). The motivation to combine Yarin et al., with Cummings would have been to provide enhanced compliance data through a system that facilitates complete integration of the essential elements to provide patient with complete and comprehensive health care (Cummings, Jr.; col. 1, lines 54-60). Motivation to additionally combine Snowden et al. would have been to allow patients to play a more active role in the management and maintenance of their health (Snowden et al.; paragraph [0102]).

[B] As per claim 2, Yarin et al., teaches wherein said data includes data regarding the side effects of a medicine and interactions between medicines (Yarin et al.; col. 3, lines 65-67 and col. 4, lines 1-11). Cummings teaches data is input by said stakeholders (Cummings Jr.; col. 4, lines 53-62, and col. 8, lines 15-21).

[C] As per claim 3, Cummings teaches wherein said data input by said stakeholders includes data regarding at least one of: the expected results from a medicine, diagnostic medical test results on a patient, data regarding the adherence to exercise, or diet regimens by a patient (Cummings Jr.; col. 8, lines 22-34, and col. 10, lines 18-26,).

[D] As per claim 4, Yarin et al. teaches said step of collecting data from said smart packages is an on-going process and said analysis to determine a compliance level is repeated periodically (Yarin et al.; col. 7, lines 15-21, and col. 49-57). Cummings teaches said step of creating a

patient report is repeated periodically (Cummings Jr.; col. 2, lines 35-42, col. 8, lines 15-34, and col. 9, lines 39-46).

[E] As per claim 8, Cummings teaches wherein said stakeholders are selected from the group including patients, doctors, insurance companies, pharmaceutical companies, pharmaceutical distributors, and healthcare providers (Cummings, Jr.; col. 1, lines 54-60).

[F] As per claim 9, Cummings teaches said insurance company providing said patient with insurance at a rate (Cummings, Jr.; col. 4, lines 53-62); said insurance company adjusting said rate for a patient based on said patient's compliance-behavior value (Cummings. Jr.; col. 8, lines 35-54); and updating said patient report with information about said adjustment in said rate (Cummings, Jr.; col. 9, lines 39-46).

NOTE: Cummings does not employ the terminology of reducing a premium or insurance rate but rather indicates that "health incentives and rewards" may be included. Cummings further indicates that such rewards or "bonuses may be credited to participants according to the extent to which they adhere to their personalized recommended preventative health program or to the extent to which their own personal draw upon health resources fall below specified levels" (Cummings, Jr.; col. 8, lines 47-54). The examiner is interpreting the "rewards and bonuses" of Cummings to be encompassing of the applicant's desire to financially reward the patient for compliance with a medical regimen.

[G] As per claim 10, Cummings teaches a method wherein said stakeholders include patients, doctors, insurance companies, pharmaceutical companies, pharmaceutical distributors, and healthcare providers (Cummings, Jr.; col. 1, lines 54-60).

[i] Regarding claims 2-4 and 8-10, the obviousness and motivation to combine as discussed with regard to claim 1 above are applicable to claims 2-5 and 8-10 and are herein incorporated by reference.

[H] As per claim 16, Yarin et al., teaches a computer-readable medium containing a data structure for storing data relating to the compliance of a patient with a medicine regimen containing data relating to a plurality of medicines (Yarin et al.; col. 5, lines 34-48, col. 5, lines 49-67, and col. 6, lines 1-5). Yarin et al., further teaches data identifying when a smart package that contains the medicine is used (Yarin et al.; col. 8, lines 49-58). Snowden et al., teaches an account for each of a plurality of patients (Snowden et al.; paragraph [0111] [0113]). Cummings teaches data identifying the medicines being taken by each a patient (Cummings, Jr.; col. 9, lines 39-52).

[i] Regarding claim 16, the obviousness and motivation to combine Yarin et al., with Cummings as discussed with regard to claim 11 above are applicable to claim 16 and are herein incorporated by reference.

[ii] Regarding the addition of Snowden et al., it would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Yarin et al., and Cummings with those of Snowden et al. Such combination would have enabled patient data, including prescriptions, to be stored in a secure repository along with other personal medical records owned and controlled by the patient such that the patient could access reports and make such reports accessible to appropriate care providers, insurers and suppliers (Snowden et al.; Abstract). The motivation to combine the teachings would have been to advantageously have an individual's healthcare records stored in a permanent database (Snowden et al.; paragraph [0074]) and to allow patients to play a more active role in the management and maintenance of their health (Snowden et al.; paragraph [0102]).

[I] As per claim 17, Snowden et al., teaches patient accounts (Snowden et al.; paragraph [0104]). Cummings teaches data input by a doctor regarding compliance by a patient (Cummings, Jr.; col. 8, lines 15-21 and lines 35-54).

[i] Regarding claim 17, the obviousness and motivation to combine as discussed with regard to claims 11 and 16 above are applicable to claim 17 and are herein incorporated by reference.

[J] As per claim 18, Yarin et al., teaches a system for disseminating medical information to increase patient compliance with a drug regimen comprising: a smart package for storing medicine (Yarin et al.; Abstract, and col. 3, lines 20-40); a means for said smart packages to interact with stakeholders through an electronic communication medium (Yarin et al.; col. 3,

lines 42-51); a means for collecting data from said smart packages and storing said data (Yarin et al.; col. 7, lines 15-21); and a data analyzing component that analyzes said data from said smart packages to determine the compliance level of the patient (Yarin et al.; col. 11, lines 10-26).

[i] Yarin et al., fails to teach a computer controlled by an administrator, a component database including information regarding a plurality of patients and medicines, storing data in a database, means for a plurality stakeholders to access data and input data into the database, generating patient reports or enabling patient access to generated reports or patient information.

[ii] However, Cummings teaches a component storing a database which includes information regarding a plurality of patients and a plurality of medicines (Cummings, Jr.; col. 4, lines 30-39, col. 5, lines 9-14, and col. 9, lines 47-52); a means for a plurality of stakeholders to access said database and input data into said database through an electronic communication medium (Cummings, Jr.; Abstract, col. 1, lines 54-60, and col. 8, lines 15-21); a means for recording input data from said stakeholders in said database through an electronic communication medium (Cummings Jr.; col. 4, lines 53-62, and col. 8, lines 15-21); and a patient report generating component that creates a patient report for each said patient (Cummings Jr.; col. 8, lines 15-34, col. 9, lines 39-46, and col. 12, lines 34-43), said patient report having data relevant to each said patient (Cummings Jr.; col. 8, lines 15-34, col. 9, lines 39-46, and col. 12, lines 34-43).

[iii] Cummings fails to teach a computer controlled by an administrator and patient access to reports through an electronic medium.

[iv] However, Snowden et al., teaches a computer controlled by an administrator (Snowden et al.; paragraph [0075] [0103); and a means for allowing each said patient to access his or her patient report through an electronic communication medium (Snowden et al.; Abstract and paragraphs [0075] [0104]).

[v] It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Yarin et al., with those of Cummings, Jr., and further with those of Snowden et al. Such combination would have resulted in a system and method capable of collecting compliance data from individual patients using a medication "Smart Tray" that is capable of monitoring and reporting to third parties a patient's compliance with various treatment regimens, including medication regimens (Yarin et al.; col. 3, lines 20-25). Further, such a system would serve to enter and store the colleted compliance data in databases (Cummings, Jr.; col. 4, lines 30-39) such that analysis of the data could serve to enhance periodic monitoring and review of a patient's adherence to health recommendations (Cummings, Jr.; col. 8, lines 22-34). Additionally, such a system would have enabled administrative control over the gathering and integration of clinical, encounter, and compliance data to be stored in a secure repository along with other personal medical records such that the patient could access reports and make such reports accessible to appropriate care providers, insurers and suppliers (Snowden et al.; Abstract and paragraph [0075]). The motivation to combine Yarin et al., with Cummings would have been to provide enhanced compliance data through a system that facilitates complete integration of the essential elements to provide patient

with complete and comprehensive health care (Cummings, Jr.; col. 1, lines 54-60). Motivation to additionally combine Snowden et al. would have been to allow patients to play a more active role in the management and maintenance of their health (Snowden et al.; paragraph [0102]).

[K] As per claim 19, Cummings teaches said component storing a database, said data analyzing component, and said patient report generating component (Cummings Jr.; col. 8, lines 15-34, col. 9, lines 39-46, and col. 12, lines 34-43). Snowden et al., teaches said computer controlled by an administrator (Snowden et al.; paragraph [0075] [0103).

[L] As per claim 20, Yarin et al., teaches a system wherein said means for collecting data from said smart packages is a base station (Yarin et al.; col. 6, lines 45-55).

[M] As per claim 21, Yarin et al., teaches a system wherein said means for allowing each said patient to access his or her patient report is a computer (Snowden et al.; paragraph [0105]).

[i] Regarding claims 19-21, the obviousness and motivation to combine as discussed with regard to claim 18 above are applicable to claims 19-21 and are herein incorporated by reference.

[5] Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yarin et al., Cummings, Jr., and Snowden et al., as applied to claim 1 above, and further in view of Aten et al.

[A] As per claim 5, Snowden et al., does not teach a compliance-behavior value or assessment assigned to a patient. While Cummings teaches allowing stakeholders to access patient data through an electronic medium (Cummings, Jr.; Abstract, col. 1, lines 54-60, and col. 8, lines 15-21), Cummings fails to teach a calculated compliance value or that a calculated compliance value is among the patient data accessible by stakeholders. Although Yarin et al., teaches the further step of analyzing data to determine a compliance-behavior level of the patient (Yarin et al.; col. 5, lines 25-32), Yarin et al., does not teach quantifying a patient's compliance-behavior level as a value or further allowing stakeholders to access a quantified compliance value or rating.

[i] However, Aten et al. teaches analyzing data to determine a compliance-behavior value of the patient (Aten et al.; col. 14, lines 67-68 and col. 15, lines 1-4).

[ii] Regarding claim 5, the obviousness and motivation to combine the teachings of Yarin et al., Cummings, and Snowden et al., as discussed with regard to claim 1 above are applicable to claim 5 and are herein incorporated by reference.

[iii] Regarding the addition of the teachings of Aten et al. it would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Yarin et al., Cummings, and Snowden et al., with those of Aten et al. Such combination would have enabled the compliance level assessment of Yarin et al. (Yarin et al.; col. 5, lines 25-32) to be enhanced by calculating several compliance scores from patient data (Aten et al.; col. 14, lines 67-68). The motivation to combine the teachings would have been help patients take medications per a prescribed schedule and to evaluate the patient's actual compliance to the regimen (Aten et al.; col. 2, lines 54-65). Further motivation would have been to provide an evaluation of patient compliance to the prescribed regimen and the probable effectiveness of the drug therapy (Aten et al.; col. 15, lines 17-25).

[B] As per claim 6, Aten et al., teaches including the steps of (a) formulating a recursive algorithm (Aten et al.; col. 16, lines 12-45); b) comparing the data regarding a patient with a pre-defined set of optimal criteria (Aten et al.; col. 15, lines 21-31); and c) adjusting the patient's compliance-behavior value as the patient's compliance improves or declines (Aten et al.; col. 16, lines 45-67).

[C] As per claim 7, Aten et al., teaches the step of analyzing data to determine a compliance-behavior value includes the step reducing the compliance behavior value to a number or a code (Aten et al.; col. 16, line 43).

[i] Regarding claims 6 and 7, the obviousness and motivation to combine as discussed with regard to claim 5 above are applicable to claims 6 and 7 and are herein incorporated by reference.

Response to Remarks

Applicant's Remarks filed 30 May 2006 have been fully considered but they are not persuasive. The Remarks will be addressed below in the order in which they appear in the response filed 30 May 2006.

Regarding Examiner's rejections of claims 11 and 14 under 35 U.S.C. 103(a), Applicant remarks:

"Yarin does not, however, disclose the use of a database which includes information regarding a plurality of patients and a plurality of medicines. The Examiner has provided the statement that "it is clear that the invention be practiced with more than a single patient participant" but provides no support for this statement. As the examiner further notes, Yarin fails to disclose the use of a database which includes information regarding a plurality of patients and a plurality of medicines."

In response, Examiner's interpretation of Yarin's intention to practice the invention with more than one patient is driven by Yarin's consistent use of patients, in the plural, throughout the reference, as evidence that more than one "Smart Tray" would be distributed to multiple patients.

Applicant further remarks that:

"Cummings does not disclose, or mention, any system or device structured to monitor patient compliance with a medication regimen. In fact, the complete statement within Cummings regarding patient monitoring reads, "the System determines from the entered data, the need for Post Treatment matters 230 such as Monitoring 231, Life Style 232, Medication 233, Weight Control 234 and Other 235." Nothing in this sentence relates to monitor patient compliance with a medication regimen using smart packages and a communication network as in Yarin. As such, the Examiner has failed to present evidence set forth with the references that support the proposed combination."

In response, Examiner's directs Applicant's attention to the teachings of Cummings at col. 1, lines 54-60, which disclose that the Cummings invention is a healthcare infrastructural system that provides for integrated interconnection and interconnection and interaction of the patient, health care provider, bank or other financial institution, insurance company, utilization reviewer and employer so as to include within a single system each of the essential participants (i.e., stakeholders) to provide patients with complete and comprehensive pre-treatment, treatment and post-treatment health care and financial support thereof (Cummings, Jr.;). In rejections of claims

1-21 of the present case, as set forth in the previous Office Action mailed 26 January 2006, and reiterated in the Present Office Action, Examiner relies Cummings' integration of systems and provision of a healthcare infrastructure that enables multiple parties, including insurance and financial entities play an active, and participatory role in the medical care and well being of enrolled patients (Cummings, Jr.; col. 1, lines 54-67). Examiner does not rely on Cummings to provide specific evidentiary support for medication compliance data collection, but rather Examiner employ's Cummings, as a secondary reference, to illustrate a well-known, integrated healthcare infrastructure.

However, Examiner respectfully submits that while medication compliance monitoring by smart packages is not explicitly set forth in exemplary fashion in the Cummings teachings, Cummings emphasizes utilizing the integrated system to integrate all aspects of "wellness", that is, of the optimization of health-inducing diet and lifestyle factors in combination with enhanced integrated diagnosis, treatment and post-treatment of illnesses and quality monitoring and enhancement systems including patterns of treatment protocols (Cummings, Jr.; col. 1, lines 60-67). Further, Cummings indicates an intention to implement a two-way flow of information for the collection of data regarding monitoring of the patient, lifestyle (adjustments), medication, weight control, and others (Cummings, Jr.; col. 14, lines 39-48). Cummings further discloses that preventative health recommendations are communicated to the participant and provision is made for the periodic monitoring and review (Cummings, Jr.; col. 8, lines 35-55). By way of example, Cummings provides a model for one such monitoring technique that could be implemented to monitor the patient's adherence to an exercise program (Cummings, Jr.; col. 8, lines 35-55).

Cummings further teaches customized health recommendations for health enhancing practices and for the periodic monitoring of participants' physical conditions, diets and lifestyle so as to identify and address incipient health problems and provide corrective measures before health problems develop (Cummings, Jr.; col. 2, lines 35-42). Examiner respectfully submits that one such lifestyle modification, should it be identified as a health concern by a healthcare provider, would be a patient's non-compliance with a medication regimen. Further, Examiner respectfully submits that Cummings' teachings of integrating well known automated monitoring systems to monitor and measure a patient's compliance with a health regimen (exemplified by Cummings exercise monitoring) into the disclose healthcare infrastructure provides ample evidence that Cummings anticipates data collection using other well known patient monitoring techniques, such as the one disclosed by Yarin et al.

Regarding Examiner's rejections under Yarin et al., in view of Cummings, Jr., Applicant remarks:

"The references do not have such a teaching, suggestion, or incentive supporting combination, but, after having examined the present application, the Examiner has identified selected elements of the present invention in the prior art, and stated that because these elements are present in the prior art, and are now disclosed in the present application."

In response, as set forth above, Examiner's interpretation of Cummings is that monitoring a patient's compliance to a medication regimen would have been among the known monitoring

techniques anticipated by Cummings at col. 8, lines 45-46. The primary teachings applied in Examiner's rejections, Yarin et al., disclose one such technique. Specifically, Yarin et al. provide for the administration of medicine in a smart tray medication dispenser that monitors a patient's compliance with various medication treatment regimens and reports the data to third parties including healthcare providers, pharmacies, and other suppliers of healthcare products and services (Yarin et al.; Abstract). Further, Yarin et al. teach that the medication compliance device may communicate with other appliances including weight scales, refrigerators, and exercise devices (Yarin et al.; col. 5, lines 51-64), indicating to the Examiner that the design of the Yarin device/system directly anticipates integrated incorporation into a multifaceted health improvement strategy, like the one specifically communicated by Cummings at col. 8, lines 35-55. Examiner respectfully submits that Yarin et al. clearly anticipate reporting data to, and receiving data from, various data processing systems and computing devices of third parties (e.g., such as the system disclosed by Cummings) in order to transfer and receive information (Yarin et al.; col. 5, lines 34-47).

Regarding Examiner's rejections of claims 12-13 and 15, Applicant remarks:

The cited passages of Aten et al. do "not disclose the collection of data regarding the expected results of a medicine." Applicant further asserts that the Examiner's cited "motivation to combine references is to gather patient compliance data to compare to the actual dosing intervals to the prescribed dosing intervals to determine how well the actual medication levels matched the prescribed levels. Even if such a motivation existed, this would not motivate one skilled in the art

to a system for collecting data regarding the expected results of a medicine. That is, tracking a patient's compliance to a drug regimen does not relate to proving information as the expected results of a medicine.

In response, Examiner directs Applicant's attention to the cited passages of Aten et al. at col. 15, lines 5-16, which disclose "Another index can be computed that measures the effectiveness of the doses that were taken." This passage, when taken in view of Aten's teachings at col. 18, lines 18-29 which state that such "calculations provide evaluation of patient compliance by highlighting the cumulative effect of under-use or over-use of drugs through the prescription period as well as analyzing overall drug intake", indicates to the Examiner that Aten's "assessment of the cumulative effect of under-use or over-use of drugs" and indices to measure the "effectiveness of the doses taken" constitute "expected results of the medicine", as claimed by Applicant.

More specifically, Aten is utilizing compliance data to generate an assessment of whether or not the prescribed drugs are maintained at effective blood levels throughout the course of treatment (Aten et al.; col. 18, lines 25-29). Examiner respectfully submits that, as evidenced by Aten, the use of compliance data to assist in the determination of actual therapeutic levels of the drugs to predict efficacy of a drug, is well known in the art.

Regarding claims 1-4, 8-10 and 16-21, Applicant remarks:

Snowden discloses a single element of the present invention. Snowden does not, however, provide a teaching, suggestion, or incentive supporting the stated combination. As such, the identified prior art is only a recitation of diverse references each of which include selected elements of the claimed invention. The Examiner's stated motivation for combining the references does not exist within the references and, as such, the Examiner is again using hindsight to improperly create a basis for a rejection."

In response, Examiner has applied Snowden merely to illustrate that enabling patient access to his or her own medical data, in its entirety, is well known in the art. Further, Examiner directs Applicant's attention to Snowden's teachings at paragraphs [0081] [0082] [0109], which indicate that among the data that are accessible to users of the system are data concerning the compliance of a patient with a prescribed regimen and physician directives.

Applicant further remarks:

"The Examiner has explained that he has interpreted "health incentives and rewards" to include financial reward; however, nothing in the cited passage indicates that there is such a financial aspect to the program."

In response, Examiner directs Applicant's attention to the cited passage of Cummings at col. 8, lines 47-55, which, as Applicant notes, states "...bonuses may be credited to participants according to the extent to which they adhere to the recommended preventative health program or

the extent to which their own personal draw upon health resources falls below specified levels." Examiner is unclear as to how, as hypothetically posed by Applicant, a piece of candy or a day off from exercise would qualify as a "bonus credited to the participant to the extent to which their own personal draw upon health resources falls below specified levels" (Cummings, Jr.; col. 8, lines 49-54). Further, in his determination that Cummings' rewards and incentives are financial, Examiner interprets the above noted passage in view of the objects of the Cummings' invention which include "provision for implementation of discretionary patient cost-sharing and/or supplementation to supplement approved fees and to obtain a selected medical treatment with a sharing of costs by the insurance company...".

Applicant further remarks:

"Thus, as Cummings as fails to disclose that an insurance company provides the patient with insurance at a rate, the insurance company adjusts the rate for a patient based on said patient's compliance-behavior value, and updates the rate for a patient based on said patient's compliance-behavior value and updates the patient report with information about the adjustment in the rate."

Applicant additionally remarks:

"Insurance companies generally impose a higher premium for an unhealthy person, e.g., a smoker, above a normal rate. Thus the smoker's "position" is lower than normal. By adjusting the insurance rate according to the present invention, the disadvantaged person is brought up to

normal. As such removal of a penalty, e.g. adjusting the insurance rate, is not the same as providing a reward."

In response, Examiner agrees with Applicant with respect to well-known premium determination strategies typically employed by insurance companies in so far as insurance companies determine premiums based on an individual's health profile. As noted by the Examiner above, Cummings emphasizes implementing a health regimen to improve the overall wellness of the participant (i.e., improvement in a participant's "position"). As also noted by the Examiner above, Cummings provides for rewards and incentives to be provided to the participant for adherence to a health improvement regimen. Further, Cummings implements such a program within a healthcare infrastructure designed to facilitate cost sharing between a patient and an insurance company (Cummings, Jr.; col. 3, lines 28-35). In light of the above noted teachings of Cummings, Examiner respectfully submits that it is reasonable to determine that Cummings (like both the Applicant and the Examiner) is also aware of well-known premium determination strategies typically employed by insurance companies. Accordingly, it is also a reasonable determination that Cummings' rewards and incentives are driven by an expected reduction of healthcare costs associated with the participant as a result of improvements in the participant's overall health (i.e., improved position/lowered risk). Examiner respectfully submits that among the mechanisms available for realization of rewards for improving one's overall health would be a lowering of premiums, as would be expected given typical insurance industry practices as applied to an improvement in a participant's overall health.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert D. Rines whose telephone number is 571-272-5585. The examiner can normally be reached on 8:30am - 5:00pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RDR

9/5/06

JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER